State of Wyoming Department of Health

Public Health TB Protocol January 2004

Public Health TB Protocol is published by the Preventive Health and Safety Division

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This document is available in alternative format upon request.

Overview:

Until 1994 Wyoming had been experiencing an increasing trend in the number of active tuberculosis cases, reaching a high of 12 cases and a case rate of 2.6 per 100,000 population that year. Since then Wyoming's trend has reversed itself, and since 1998 Wyoming has most often had the fewest number of active TB cases and the lowest TB case rate of any State in the Country. This is due in part to the diligent efforts of all the partners involved with TB prevention and control, including public health nursing and others included in this Protocol. But, low prevalence of active tuberculosis can be a two-edged sword, and continued effort must be made to maintain a high index of suspicion for this communicable disease.

The TB Program's primary objectives are to (1) obtain a TB case rate of < or = 1.0 case per 100,000 population, and (2) maintain a preventive therapy completion rate (i.e., the percentage of people who start preventive therapy who complete at least a 6 months course) of > or = 85%. Wyoming has been successful in meeting these objectives each year since 1997.

Our highest priorities are to (1) identify and treat all patients who have active tuberculosis, (2) find and screen contacts of infectious TB cases, (3) offer preventive therapy to those who are infected with *M. tuberculosis*, and (4) screen members of high risk populations to find those persons who have latent TB infection or active disease. 2003 recommendations of the American Thoracic Society, CDC and the Infectious Diseases Society of America regarding the treatment of tuberculosis suggest that the Health Department is ultimately responsible for ensuring that adequate diagnostic and treatment services are available, and for monitoring the results of therapy. Further, successful treatment is the responsibility of the managing provider, or public health program, or both, rather than the patient.

Accomplishing our objectives and priorities will continue to be dependent upon adherence to the guidelines contained in this Protocol. The body of this document describes the role of Public Health Nursing, the role of the Public Health TB Laboratory, the role of the Attending Physician, the role of the County Health Officer, the role of the regional Disease Intervention Specialists, and the role of the State TB Program Coordinator. Also included are discussion of the concept of Confidentiality (especially in light of HIPAA), and response to an Outbreak Situation. A brief Bibliography of pertinent references is included at the end. Forms currently used by the TB Program are found in the Appendix. The input of the Wyoming TB Advisory Committee is acknowledged and appreciated.

Significant progress has been made in the various aspects of TB surveillance, prevention and control since the prior Protocol was distributed in June 2000. CDC recommendations have changed, new medications have been explored for the treatment of TB, and Wyoming has developed a TB website: http://wdhfs.state.wy.us/tb

Telephone numbers of Wyoming Department of Health personnel referred to in this Protocol are (1) State Health Officer (307) 777-6340, (2) State Epidemiologist (307) 777-7958, (3) Public Health Laboratory (307) 777-7431, and (4) State TB Program Coordinator (307) 777-5658. Confidential FAX for the reporting of active tuberculosis is (307) 777-5573. This Protocol replaces the one distributed in June 2000.

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Role of Public Health Nursing:

The majority of medical care in Wyoming is provided by private sector physicians and their associates, and the State TB Program advocates that private attending physicians will have primary responsibility for the care of tuberculosis patients. County Health Officers and Public Health Nursing become the secondary source of care when the patient has no private attending physician or no physician in the community is willing to provide this care. American Thoracic Society/CDC/Infectious Diseases Society of America guidelines published in 2003 clearly place the responsibility for successful treatment of the TB patient on the managing private provider, or public health program, or both - rather than the patient. Public Health Nursing's areas of responsibility include:

1. Screening for TB infection via the Mantoux skin test.

- A. Administering the skin test, reading induration, and identifying converters and reactors according to the most recent CDC guidelines and State Nursing Policy (found in the Appendix).
- B. Reporting positive PPDs to the TB Program Coordinator.
- C. Ordering Purified Protein Derivative (PPD) and TB syringes from the TB Program Coordinator in quantities sufficient to assure a two month supply is available within each County. [Order these by calling (307) 777-5658.] An open multi-dose vial of PPD should not be kept more than 30 days. Currently we are using Aplisol from King Pharmaceuticals.
- D. Using the two-step procedure for initial screening, when periodic (e.g., annual) retesting is required and the individual has not been tested within the prior 12 months, and the first test is negative. The two-step procedure is intended to allow a differentiation between "old" and recent infection with *M. tuberculosis*. The second skin test is administered 1-3 weeks after the first Mantoux test. Induration (not erythema) is measured 48-72 hours after the skin test was administered and is measured transversely to the long axis of the forearm. Results are recorded in millimeters.
- E. The February 8, 2002 **MMWR** "General Recommendations on Immunization" suggest that PPD and measles containing vaccine can be administered at the same time, but if the measles (or other live virus vaccine) has been administered recently, PPD screening should be delayed greater than or equal to 4 weeks after vaccination. Wyoming adopted a policy in May 2002 which discourages routine skin testing of children, with certain exceptions. These recommendations are found in the Appendix.

2. Functioning as the agent of the physician in securing the necessary diagnostic studies for the TB infected or infectious patient.

- A. Identifying the primary care physician and coordinating care with him/her.
- B. Facilitating obtaining single-view PA chest x-ray exams, including getting pre-authorization for payment by the TB Program where the patient has no money, no

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insurance, and no Medicaid. Obtain this pre-authorization by calling (307) 777-5658.

C. Facilitating obtaining at least a baseline Liver Function Test (LFT) where the patient

- is HIV positive, is pregnant, is in the immediate postpartum period, has a history of chronic liver disease, has risk factors for hepatitis, or uses alcohol regularly. Baseline liver function testing is not routinely indicated for most patients. Obtain payment authorization from the TB Program where the testing is done by Quest Diagnostics and the patient has no money, no insurance, and no Medicaid. Our Quest account number is 08445. Obtain the pre-authorization by calling (307) 777-5658. A new authorization number is required for each patient for each LFT paid for by the TB Program. Should either the SGOT or SGPT liver enzymes reach a level of 5 times the upper limit of the normal range for asymptomatic patients or 3 times the upper limit of the normal range in the presence of symptoms, CDC recommends that therapy be discontinued. Consult the physician and the State TB Program for recommendations regarding the resumption of therapy once these liver enzymes have returned to within the normal range.
- D. Sputum collection when the patient is symptomatic or has an abnormal chest x-ray. Sputum collection should be done in an appropriate environment, such as a physician's office or the local hospital, but public health nursing may be called upon to perform this function. Sputum collection kits are available from the State Public Health Laboratory by calling (307) 777-7431. Sputum samples should be collected one per day preferably first thing in the morning on three consecutive days, and submitted to the State Public Health Laboratory for AFB smear and culture. At a minimum, an "N-95" respirator (i.e., one that has received an N-95 certification from the National Institute of Occupational Safety and Health) must be worn when collecting sputum specimens. The TB Program currently provides public health offices with 3M #1860 masks upon request. Be sure the mask is worn correctly and provides a proper facial seal. Follow other safety precautions, such as obtaining the specimen out-of-doors, when possible.

3. Receiving and distributing TB medications. (Requires a physician's prescription.)

- A. The individual with latent TB infection should be evaluated for preventive therapy by a physician (or nurse practitioner or certified physician's assistant) and, if appropriate, receive isoniazid (INH) for 6-9 months. Current CDC recommendations suggest that 9 months of INH is optimal, but that 6 months of INH is the minimum. Alternatively, 4 months of rifampin (with or without INH) may be used for preventive therapy.
- B. Since INH depletes the body's supply of vitamin B-6, physicians often prescribe pyridoxine (B-6) as replacement therapy to go along with the INH.
- C. The Wyoming TB Program follows the new ATS/CDC/IDSA recommendation that active TB cases, both pulmonary and extra-pulmonary, be initially placed on four anti-TB drugs at least until the results of susceptibility/resistance testing are known. These are (1) isoniazid (INH), rifampin (RIF), pyrazinamide (PZA), and ethambutol

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(EMB). See the section on HIV and TB for a discussion of the use of rifabutin (RFB) in place of rifampin for HIV/TB patients on protease inhibitors and/or Nonnucleoside Reverse Transcriptase Inhibitors.

- D. The initial phase of treatment for active TB consists of 2 months of treatment with the four first-line medications cited above, followed in most instances by a continuation phase lasting 4 months with two drugs (INH and RIF). Where the active TB case is smear and culture negative (but meets CDC's clinical case definition), and the patient does not have HIV infection, the continuation phase can be shortened to 2 months of INH and RIF (for a total length of therapy of 4 months).
- E. For patients who have cavitation on the initial chest x-ray <u>and</u> whose 2-month culture is positive, CDC recommends that the continuation phase be extended by 3 months, and that the total duration of treatment should be 9 months.
- F. In 1994, the TB Program began stocking RIFAMATE, a combination capsule consisting of isoniazid and rifampin. Use of RIFAMATE is recommended, especially where Directly Observed Therapy (DOT) is not feasible, and minimizes the possibility of mono-drug therapy. RIFAMATE is not formulated for use when therapy is administered intermittently (e.g., two or three days a week).
- G. Where ethambutol (EMB) is part of the regimen, its use usually necessitates baseline and periodic visual acuity testing, which requires a physician order.
- H. Regardless of whether the patient is being treated for active TB disease or latent TB infection, the patient should be monitored by monthly visits for the duration of therapy. ATS/CDC/IDSA recommendations include (1) establishing an individualized care plan, (2) culturally appropriate case management, (3) assignment of responsibility to an individual case manager, and (4) tracking patients who move from one jurisdiction to another before completing therapy.
- I. TB medications are currently provided without charge by the TB Program, regardless of ability to pay, upon receipt of a prescription. Verbal orders are not routinely accepted. The initial medication supply (usually three months worth) is accompanied by (1) a **Tuberculosis Communication Exchange** form, which must be completed by the provider receiving the medications and returned to the TB Program Coordinator, and (2) an **Isoniazid Check List**, which must be reviewed with the patient and kept in the patient's file. If the patient is on other medications, the PHN must assess for adverse reactions to those drugs, using the PHN Clinical Pathway (found in the Appendix).
- J. Public Health Nursing should be aware of their patients' needs for medications, and should communicate with the TB Program Coordinator when a refill is needed. Call (307) 777-5658. TB medications are normally delivered by United Parcel Service, which requires the availability of a physical street address (as opposed to a Post Office box).
- K. Successful completion of therapy is determined by both the total number of doses taken and the duration of therapy. For example, the 6-month daily regimen for active TB disease should consist of two months initial treatment with four drugs (56

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doses) followed by four months with two drugs (126 doses) for a total of 182 doses. Consistent with this, getting the patient to complete at least six months of therapy within a maximum time frame of nine months is considered satisfactory by CDC. If the length of therapy is nine months, then the maximum time frame for successful

- completion would be twelve months.
- L. The earlier the interruption in therapy, and the longer its duration, the greater the need to restart therapy from the beginning. This decision is made on a case by case basis; however, a break of longer than 14 days suggests a need to restart.

4. Directly Observed Therapy (DOT).

- A. Directly Observed Therapy (DOT) is widely accepted as the most successful way of assuring that TB patients complete an adequate course of therapy, and is now the standard of care. While there is no foolproof way of predicting who will or will not exhibit adherence in taking his/her medications, the following characteristics have been shown to be indicative of the need for Directly Observed Therapy:
 - * Alcoholism
 - * Having Drug-resistant TB
 - * Living Alone
 - * Previous TB Treatment
 - * Substance Abuse

- * Being HIV Seropositive
- * Homelessness
- * Personal/Family Crisis
- * Senility
- * Unemployment
- B. Directly Observed Therapy will be provided to confirmed or "suspect" TB cases (1) when requested by the patient's private physician, (2) when ordered by the State Health Officer or County Health Officer, (3) when the patient has demonstrated non-adherence to self-administered therapy, (4) when the patient is in an institutional setting such as a hospital, nursing home, or correctional facility, or (5) when required by the State TB Program.
- C. DOT means watching the patient ingest his/her TB medications five working days per week. This must continue for two months or until the patient is no longer infectious, whichever is longer. TB medications must be taken daily for at least the first month of therapy. After the first month, TB medications may be given intermittently (i.e., two or three times weekly). DOT is required whenever TB medications are given intermittently.
- D. Rarely, there will be circumstances where DOT may be required for a patient with latent TB infection.
- E. Public Health Nurses may provide DOT directly, or it may be delegated to another appropriately trained staff person. Relying on a family member to perform DOT is discouraged. During DOT visits, the patient should be questioned regarding signs and symptoms of drug toxicity. Any such findings should be documented and reported to the attending physician.

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5. Contact Investigation.

A. In a contact investigation, people who were exposed to someone who has active infectious TB disease are identified and evaluated for TB infection and disease.

- It includes the provision of appropriate treatment, including assuring patient adherence and completion of therapy. It should be done whenever a patient is found to have or is suspected of having infectious TB disease. (AFB seen on sputum smear or severe cough in a patient with a cavitary chest x-ray are enough evidence to warrant initiation of a contact investigation.)
- B. County PHN offices are responsible for assuring that complete contact investigations are done for TB cases residing in their counties. Requests for assistance from the regional Disease Intervention Specialists may be made to the TB Program Coordinator.
- C. The contact investigation should begin no more than 3 working days after the index case is reported to the health department. Close contacts should be examined within 7 working days after the index case has been diagnosed or the index patient has been interviewed.
- D. A <u>contact investigation</u> is conducted around an index active TB case. A <u>source case investigation</u> is done when active tuberculosis is found in a young child or when a cluster of recent skin test converters is discovered both indicative of recent transmission.

E. The Steps in a Contact Investigation are:

- (1) <u>Medical Records Review</u>. Determine the site of disease, the date symptoms began, smear and culture results, chest x-ray (or CT scan) results, when TB treatment started (i.e., medications, dosage, and start date), TB skin test date and result, DOT or self-administered therapy, and any history of previous treatment. Gauge the infectiousness of the patient, and the probable period of infectiousness.
- (2) <u>Patient Interview</u>. Use this to begin establishing a relationship of trust with the patient. Ask about symptoms, places where the patient has been while infectious, and identify contacts. Use this opportunity to provide patient education about TB. Wear the appropriate N-95 respirator.
- (3) <u>Field Investigation</u>. Visit the patient's home, workplace (if any), and sites of recreation. Skin test the close contacts. A close contact is a person who had prolonged, frequent contact with the patient while he/she was infectious.
- (4) <u>Risk Assessment for TB Transmission</u>. Gauge the infectiousness of the patient, the characteristics of his/her environment, and the nature of contact.
- (5) <u>Prioritization of Contacts</u>. Determine who the close contacts are. Include in this group those who are high risk contacts (e.g., children less than 4 years old, those with compromised immune systems, and those with certain medical conditions such as diabetes mellitus which increase their risk of going to active disease once infected with *M. tuberculosis*).
- (6) <u>Evaluation of Contacts</u>. Get a medical history and Mantoux skin test. Baseline PPD and repeat 10-12 weeks post exposure for those testing negative on the baseline test.

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Use > or = 5 millimeters of induration as the cut-off for a positive skin test. Chest x-ray examination if the contact is symptomatic

(7) <u>Treatment and Followup of Contacts</u>. For those who skin test positive, refer for a single-view chest x-ray. For those with an abnormal chest x-ray and/or symptoms

- obtain sputum samples for submission to the State Public Health TB Laboratory. Counsel infected contacts and refer them to a physician for preventive therapy. Note that preventive therapy should be given to any infected contact regardless of his/her age. Follow the infected contact to assure completion of therapy.
- (8) <u>Decision About Whether to Expand Testing</u>. The decision about expanding the contact investigation beyond the close contacts depends on evidence of recent transmission. The following constitutes evidence of recent transmission:
 - (a) A high infection rate among contacts.
 - (b) Infection in a young child.
 - (c) A skin test conversion in a contact.
 - (d) A secondary case of TB disease, especially one with a matching DNA fingerprint.

Where there is evidence of recent transmission among the first group of close contacts, testing should be expanded to other contacts. Use the **Concentric Circle Approach** (see the diagram of this in the Appendix). In Wyoming, the positive reactor rate among groups judged to be at-risk for TB infection or disease is always less than 2%. The contact investigation can cease when the percentage of contacts testing positive approaches this rate. If in doubt, consult with the TB Program Coordinator, the State Epidemiologist, or the State Health Officer.

- (9) Report to the State TB Program. Keep the TB Program Coordinator informed of what's going on. Complete the Contact Investigation Worksheet of New Active or Suspect Cases of Tuberculosis, and send a copy to the TB Program Coordinator. Public Health Nurses may be asked to complete the CDC Management Report entitled Follow-up and Treatment of Contacts to Tuberculosis Cases as part of Wyoming's obligation to report to CDC under terms of our federal cooperative agreement.
- (10) Evaluation of Contact Investigation Activities. After the contact investigation is complete, review the process and outcome, and see if the procedure used should be modified to improve effectiveness. Note that with some exceptions, the general procedure described above applies to a source case investigation as well as a contact investigation.

6. HIV and TB.

A. In otherwise healthy individuals, the lifetime risk of progressing from latent TB infection to active disease is 10% without treatment. In HIV/AIDS patients this risk is increased to 7-10% per year. Offering all active TB cases HIV testing is essential. Conversely,

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all HIV/AIDS patients should be offered TB skin testing. Each individual with a positive PPD should be evaluated for HIV risk factors, and if present, offered HIV counseling and testing. HIV risk factors include:

- (1) Unprotected sex.
- (2) Multiple sex partners.
- (3) Injectable drug use (including sharing of drug paraphernalia).
- (4) Having received a blood transfusion before 1985.
- (6) Hemophilia or other blood disorders
- (7) Having received transplanted tissues or organs.
- (8) Artificial insemination.
- (9) Being born to an HIV+ mother, or having been breast-fed by an HIV+ mom.
- (10) Persons with sexually transmitted diseases.
- (11) Hepatitis B or C.
- (12) Occupational exposure (e.g., health care worker or clinical lab employee).
- B. Knowing the HIV status of TB infected and active TB disease cases is important, because it affects skin testing interpretation and can affect decisions about the length of therapy.
- C. CDC published guidelines entitled Prevention and Treatment of Tuberculosis Among Patients Infected with Human Immunodeficiency Virus: Principles of Therapy and Revised Recommendations in the October 30, 1998 Morbidity and Mortality Weekly Report (MMWR). These guidelines recognize that HIV seropositive patients were being treated with Protease Inhibitors and Nonnucleoside Reverse Transcriptase Inhibitors (NNRTIs), and that this made the treatment of TB in these patients very complex. These guidelines were subsequently revised by CDC in a Notice to Readers entitled <u>Updated Guidelines for the Use of Rifabutin</u> or Rifampin for the Treatment and Prevention of Tuberculosis Among HIV-infected Patients taking Protease Inhibitors or Nonnucleoside Reverse Transcriptase Inhibitors, published in the March 10, 2000 MMWR. This subject is further addressed in the newest ATS/CDC/IDSA recommendations on the Treatment of Tuberculosis published in the June 20, 2003 MMWR (Vol. 52 / No. RR-11). A detailed discussion of these guidelines is beyond the scope of this Protocol, but the lesson for Public Health is that management of HIV-infected patients taking Protease Inhibitors or NNRTIs and undergoing treatment for active TB with rifabutin or rifampin should be directed by, or conducted in consultation with, a physician with experience in the care of patients with these two diseases

7. Anergy Testing.

A. Effective with publication of the September 5, 1997 <u>Anergy Skin Testing and Preventive Therapy for HIV-Infected Persons: Revised Recommendations</u> in the

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MMWR, CDC no longer advocates the routine use of anergy testing because the usefulness of anergy testing has been found to be limited due to problems with standardization and reproducibility, and low risk for TB associated with a diagnosis of anergy. Therefore, the Wyoming TB Program does not stock Mumps or Candida

- (the only two FDA-approved Mantoux method anergy skin test antigens).
- B. Should a physician insist upon use of anergy testing to either demonstrate anergy or confirm the results of PPD testing, he/she should be referred to Aventis (formerly Connaught) for Mumps Skin Test Antigen at (800) 822-2463, or to ALLERMED for Candida albicans Skin Test Antigen [Candin] at (800) 221-2748.
- C. An induration of 5 millimeters or more constitutes a positive anergy test, suggesting that the person is <u>not</u> anergic. The Mantoux method should be used by the physician when anergy testing is administered.

Role of the Public Health Laboratory:

The State Public Health TB Laboratory supports the functioning of the Wyoming TB Program, and the availability of its services in identifying acid fast bacteria (AFB) on smear and *Mycobacterium tuberculosis complex* on culture is seen as critical to successful surveillance for this disease.

Wyoming Department of Health Reportable Diseases regulations require that active tuberculosis be reported to the State within 24 hours of diagnosis, and that the entity reporting submit an isolate to the Public Health Laboratory. Smears are reported out to the referral source and to the TB Program within 24-48 hours of specimen receipt. Positive AFB smears are sent to National Jewish Center for amplified testing. New technology, the MB/BacT system, monitors specimens electronically and rapidly flags specimens ready for probing. Specimens are probed for *M. tuberculosis complex* and *M. avium complex*. Cultures are reported out to the referral source and the TB Program within 3-4 weeks of specimen receipt. An initial positive culture is sent to National Jewish Center for susceptibility testing. Drug susceptibility testing must be done on at least the first isolate from each culture positive TB case.

To facilitate use of the Public Health TB Lab by Wyoming providers, specimen collection/mailing containers are provided by the TB Laboratory. These are provided free of charge and with return postage paid. Call the Public Health Laboratory at (307) 777-7431 to obtain these. Currently there is no charge for TB testing done by or through the State Public Health TB Laboratory.

Historically, much of the TB lab work has left Wyoming for out-of-state reference laboratories. Reporting of results to the TB Program by these out-of-state labs is problematical. Surveillance and initiation of contact investigation suffer. Largely through funding from various programs within CDC, the capabilities of the State Public Health Laboratory have been enhanced, enabling full-time staffing and better customer service. It is incumbent upon members of the Public Health family in Wyoming to promote the State Public Health Laboratory and encourage maximization of its use. We anticipate the day when DNA fingerprinting will be available for each culture positive TB case.

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Confidentiality:

The concept of "confidentiality" is very important to TB surveillance, prevention and control in

Wyoming. It is the basis on which a relationship of **trust** is formed between the TB patient and the members of the health care team. Trust is essential to assuring the patient's adherence to a lengthy regimen of anti-TB medications, and it is key to successful identification of contacts.

The Wyoming Department of Health has created an <u>Information Practices</u> Rule (filed 7/12/94), requiring confidentiality of records and information. Written consent is required for release of patient information, except (1) to medical personnel to the extent necessary to meet a bona fide medical emergency, (2) to qualified personnel for scientific research, management audits, or program evaluations, but such personnel may not identify directly or indirectly any individual in any such report, audit or evaluation, (3) to any part of the health care rehabilitative system within the State of Wyoming that has a legitimate need for the record to further treatment of the individual who is the subject of the record, and (4) to **officers or employees of the Department** who have a clearly established need for the record as a routine use in order to carry out legal duties of administering or enforcing the laws of the Federal Government, the State of Wyoming, or any of its political subdivisions.

W.S. 35-4-107 sets forth the right of the State Health Officer or his designee to collect and provide information which may include the name of the person suffering from disease only to the County Health Officer or health representatives where disease control efforts are required. For the purposes of W.S. 35-4-107, "health representatives" means those health care workers assigned by federal, state or local health authorities to assist with disease control and investigation efforts under the direct supervision of the State Health Officer or his designee and local health officer. There may be review of medical records by the State Health Officer, his designee, or their designated health representatives to confirm diagnosis, investigate causes or identify other cases of disease conditions in a region, community or workplace in the State. The review of records may occur without patient consent, but shall be kept confidential and shall be restricted to information necessary for the control, investigation and prevention of disease conditions dangerous to public health..

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) was adopted to ensure health insurance coverage after leaving an employer and also to provide standards for facilitating health care related electronic transactions. Congress incorporated into HIPAA provisions that mandated adoption of federal privacy protections for certain individually identifiable health information. The HIPAA Privacy Rule (Standards for Privacy of Individually Identifiable Health Information) dictates that "covered entities" (i.e., the Wyoming Department of Health) must observe certain requirements when using or disclosing "protected health information" (PHI). Among other things, effective April 14, 2003, HIPAA requires that:

A. Individuals may request access to inspect or to obtain a copy of the information maintained by a Program, as long as the information is in a designated record set.

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- B. Individuals may request an amendment of their information.
- C. Individuals may request that the Department restrict disclosures of their health information.
- D. Individuals may request to receive communications by alternate means or at alternate locations.

- E. Individuals may request to receive an accounting of the Use and Disclosures the Program has made other than disclosures made for normal business operations or for disclosures the individual has authorized. The report will contain up to six years of disclosures. The first day of tracking disclosures began on April 14, 2003.
- F. The Department will provide a means to protect all confidential information in electronic or paper form.
- G. The Department will not use or disclose more than the minimal necessary amount of confidential information to provide service to its clients. Information necessary for treatment, payment or operations (TPO) is not covered by HIPAA.
- H. The Department will provide and document privacy education, develop and maintain privacy and confidentiality policies and procedures, provide clients with a Notice of the Department of Health's Practices, and designate a privacy official to administer a complaint process for clients.

The Wyoming TB Program will observe the HIPAA policies and procedures adopted by the Wyoming Department of Health. PHNs should follow PHN HIPAA policy for their patients.

The TB Program recognizes the importance of patient confidentiality. However, active tuberculosis is an infectious communicable disease of considerable public health consequence. In the course of conducting TB control activities, some patient rights may be overridden in the interest of protecting the public's health. The patient's right to autonomy, for example, may be overridden in the interest of protecting others who may be harmed by the patient's decisions. Case reporting, by name, is required for various communicable diseases including TB in Wyoming. The sharing of surveillance information between the HIV/AIDS and TB Programs within the same health department is necessary to conduct both TB and HIV/AIDS surveillance programs and allow for adequate investigation of TB and HIV/AIDS cases. Where TB surveillance, prevention and control involve HIV/AIDS, the more stringent confidentiality requirements of the HIV/AIDS Program apply.

Consistent with the above, below are listed some suggested guidelines:

- A. Records containing patient names and other identifying information should be kept in closed and locked files, except when being used by public health staff.
- B. Any surveillance information sent through the mail should be in a sealed envelope marked "confidential" and addressed to a specific individual.
- C. FAXed information should be sent to the confidential FAX number (307) 777-5573 and should be addressed to a specific individual.
- D. The use of patient identifiers (e.g., names) should be limited in e-mail communications.

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- E. With regard to requests for information from the public, (1) sensitive program or patient issues or records should not be discussed, (2) the name of the patient, contact, converter, or reactor should not be released, and (3) public health staff should not confirm or deny that a particular individual has been reported as an active TB case.
- F. Statistical data released to the public must be in summary form, such that no individual

- can be directly or indirectly identified.
- G. Access to electronic databases should be restricted to designated staff, and include the use of passwords.
- H. In the field, use discretion when making patient visits and conducting patient interviews in private.
- I. Minimize the necessity, use and content of written messages left for patients posted at their places of residence. When this becomes necessary, leave any written message in a sealed envelope marked "confidential" and addressed to a specific person.
- J. Do not leave sensitive or confidential information with a neighbor or friend.
- K. When in doubt, first protect confidentiality; then, consult the TB Program Coordinator, the State Health Officer, or State Public Health Nursing.

Role of the Attending Physician:

It is the expectation of the Wyoming TB Program that the private attending physician will assume primary responsibility for his/her patient's tuberculosis infection or active disease management. This includes screening, chest x-ray, sputum collection and AFB testing, anti-TB medication prescriptions, liver function monitoring, visual acuity checks (when ethambutol is part of the drug regimen), and following their patients monthly where TB medications are being given. There is a mutual responsibility between the attending physician and Public Health Nursing at the county level to assure good communication and patient management. If the physician would like Public Health Nursing at the county level to assume responsibility for patient monitoring, education or directly observed therapy, this can be arranged through a written order to the local Public Health Nursing office.

The attending physician can diagnose active TB disease based upon a culture which is positive for *M. tuberculosis complex*, or he/she can make the diagnosis clinically. Clinical diagnosis of tuberculosis (without a confirming culture) can be made when (1) the patient has a positive TB skin test, and (2) there exist signs and symptoms consistent with tuberculosis (such as an abnormal chest x-ray), and (3) treatment with two or more anti-TB drugs is given and the patient is improving. It is the responsibility of the attending physician to report any case of suspected or confirmed TB disease, pulmonary or extra-pulmonary, to the State Health Officer or his designee promptly (see W.S. 35-4-107). State Health Officer designees include the State TB Program Coordinator, the State Epidemiologist, and County Health Officers. All physicians in Wyoming are encouraged to utilize the TB testing services of the State Public Health Laboratory.

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Role of the County Health Officer:

W.S. 35-1-240 empowers the State Health Officer and others under his direction and supervision to (1) investigate and control the causes of epidemic, endemic, communicable, occupational and other diseases, and (2) establish, maintain and enforce isolation and quarantine. The State Health

Officer can delegate these powers to County Health Officers (CHOs).

Wyoming Statutes 35-4-101 through 35-4-134 in sum provide an overview of the responsibilities of a County Health Officer, who is a physician licensed to practice medicine in Wyoming. What is expected of a County Health Officer with regard to TB parallels what is expected of a County Health Officer regarding Sexually Transmitted Diseases. W.S. 35-4-132 through 35-4-134 permit the County Health Officer to (1) administer, refer or recommend appropriate treatment, (2) isolate an infectious individual, (3) provide a physical examination, (4) require the individual to seek adequate treatment, (5) order necessary testing, (6) arrange for education and counseling, and (7) identify contacts of the infected individual.

The County Health Officer is expected to become involved in the State's TB Control Program. This may take the form of oversight, where patient care is directed (i.e., medical management is provided) by a private physician. The County Health Officer may be called upon to provide medical direction himself, where the patient has no physician or where no other physician in the community is willing to provide this. Where medical speciality and/or limitations imposed by professional liability insurance coverage preclude a County Health Officer from providing this care directly, the CHO is authorized to direct another physician in the community to provide this care. The County Health Officer will assist the State Health Officer with the issuance of any necessary quarantine procedure. The County Health Officer should be aware of the TB testing capabilities of the State Public Health Laboratory, and promote its use when appropriate.

When the County Health Officer needs assistance, he/she should contact the State Health Officer, the State Epidemiologist, the State TB Program Coordinator, the Disease Intervention Specialist in his/her region, and/or Public Health Nursing. Conversely, it is appropriate for a Public Health Nurse or others listed here to contact the County Health Officer for assistance.

Role of the Disease Intervention Specialists:

The HIV/AIDS, STD and TB Programs recognize the importance of cross utilization of regional field personnel to expedite the services provided by these programs. Given the large geographical area and dispersed population that are Wyoming, the services of the regional Disease Intervention Specialists are felt to be essential to a successful TB control program. The TB responsibilities of the Disease Intervention Specialists are to assist the State TB Program Coordinator by:

A. Ensuring that counties perform contact investigations, and report results of these to **Wyoming TB Protocol**Page 14.

- the State TB Program Coordinator: (1) initial reports within 3 weeks of the start of the contact investigation, and (2) final reports within 3.5 months.
- B. Getting involved with TB screening efforts surrounding unexplained clusters of TB skin test converters (e.g., a source case investigation).
- C. Presenting TB educational programs, at the request of the TB Program Coordinator, County Health Officer, Public Health Nurse, Infection Control Staff, or private provider.

D. Providing timely liaison and consultation with providers, including Public Health Nursing.

Role of the State TB Program Coordinator:

Any Tuberculosis Control Program should have as its top priorities (1) identification and treatment of all patients who have active tuberculosis, (2) finding and screening contacts of infectious TB cases, (3) offering preventive therapy to those with latent TB infection, and (4) screening members of high risk populations to find those who have TB infection or disease. The State TB Program Coordinator organizes the TB resources (in terms of personnel, finances and supplies) within Wyoming to create a comprehensive program to accomplish the above, monitors the program, and causes it to be evaluated. This includes the following:

- A. Having in place a TB protocol acceptable to the State Health Officer and/or State Epidemiologist.
- B. Administrative oversight of the management of persons with TB disease, or suspected of having TB disease, as the agent of the State Health Officer.
- C. Assuring that persons with clinically active disease are identified and reported.
- D. Assuring that persons with latent TB infection are identified, especially where assistance is sought from the TB Program for preventive therapy.
- E. Working with the State Public Health Laboratory to assure that TB testing meets the needs of TB patients and physicians providing care to these patients.
- F. Data collection and analysis, with periodic reporting in appropriate publications such as the <u>Epidemiology Bulletin</u> and/or <u>Preventive Health Update</u>.
- G. TB training and education.

In addition, the TB Program Coordinator is responsible for the following:

- A. Logistical support for and consultation with the county public health nursing offices, State Public Health Nursing, hospitals, nursing homes, private practitioners, substance abuse treatment programs, HIV/AIDS Program, migrant farm worker programs, Wyoming Department of Corrections, county detention facilities, homeless healthcare programs, and private citizens needing assistance with TB prevention and control.
- B. Ordering, receiving and distributing TB medications and diagnostic materials, as the agent of the State Health Officer.

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- C. Authorizing payment for diagnostic chest x-rays and liver function tests.
- D. Intrastate and interstate notification of in and out migration of TB infected and infectious individuals.
- E. Field visits throughout Wyoming, as needed to assure that TB prevention, control and elimination efforts are promoted and sustained.
- F. Maintenance of the Wyoming Tuberculosis Registry.
- G. Creation and staffing of a state-wide TB Advisory Committee.
- H. Administrative functions such as grant writing, budgeting, and reporting of

- TB cases to the Centers for Disease Control and Prevention.
- I. Participation in appropriate external "trade" organizations, such as the National Tuberculosis Controllers Association, the Midwest TB Controllers Association, and/or the Northern Rocky Mountain TB Controllers group.

Response to a TB Outbreak Situation:

In Wyoming, two or more related active tuberculosis cases could constitute an outbreak situation. Internally, Wyoming has several resources that can be brought to bare upon such a situation, including (1) the State TB Program [(307) 777-5658], (2) the State Epidemiologist [(307) 777-7958], (3) the State Health Officer [(307) 777-6340], (4) the State Public Health Laboratory [(307) 777-7431, (5) the County Health Officer in the affected county, (6) the regional Disease Intervention Specialists, and (7) Public Health Nursing both at the County and State levels. Externally, the State TB Program can bring in the services of the Division of TB Elimination at CDC, National Jewish Center TB Laboratory, consultation from the Francis J. Curry National Tuberculosis Center, and consultation with TB control program managers from around the United States.

The preferred procedure when an outbreak is suspected or confirmed is to (1) contact the State TB Program, and (2) contact the County Health Officer and the Public Health Office in the affected county. If the State TB Program Coordinator is unavailable, contact the State Epidemiologist. The Wyoming Department of Health maintains a **Disease and Outbreak Hotline: 1-888-996-9104**, which can be used for epidemiological, clinical, and laboratory consultation and assistance for any illness, including TB. The State Epidemiologist, after any necessary consultation, will determine the need for Epidemic Intelligence Service (EIS) assistance, and he or the State TB Program Coordinator will contact Wyoming's TB Program Consultant at CDC. The request for assistance from the Division of TB Elimination at CDC may result in technical assistance (e.g., epidemiologic, laboratory or information technology) or additional financial resources necessary to stop transmission and halt the outbreak. The State TB Program Coordinator will inform the Acute Illness and Injury Control Section Chief so that maximum input can be achieved. The State TB Program Coordinator also has access to the network of State TB Controllers which may be needed to track contacts across the country.

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Wyoming Department of Health

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